

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER NY060155-VAN-ES
INTERNATIONAL APPLICATION NO. PCT/NL2004/000552		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) Unknown 811/E 26078
INTERNATIONAL FILING DATE 4 August 2004		PRIORITY DATE CLAIMED 5 August 2003
TITLE OF INVENTION "USE OF RECOMBINANT OR SYNTHETIC GELATIN-LIKE PROTEINS AS STABILISER IN LYOPHILIZED PHARMACEUTICAL COMPOSITIONS"		
APPLICANT(S) FOR DO/EO/US VAN ES, Andries, Johannes, Jozef; BOUWSTRA, Jan, Bastiaan; TODA, Yuzo		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.		
2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.		
3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.		
4. <input checked="" type="checkbox"/> The US has been elected (Article 31).		
5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))		
a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).		
b. <input type="checkbox"/> has been communicated by the International Bureau.		
c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).		
6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).		
a. <input type="checkbox"/> is attached hereto.		
b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).		
7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))		
a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).		
b. <input type="checkbox"/> have been communicated by the International Bureau.		
c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.		
d. <input type="checkbox"/> have not been made and will not be made.		
8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).		
9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).		
10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).		
Items 11 to 20 below concern document(s) or information included:		
11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.		
12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.		
13. <input checked="" type="checkbox"/> A preliminary amendment.		
14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.		
15. <input type="checkbox"/> A substitute specification.		
16. <input type="checkbox"/> A power of attorney and/or change of address letter.		
17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.		
18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).		
19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).		

1AP20 Rec'd PCT/US 02 FEB 2006

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) Unknown		INTERNATIONAL APPLICATION NO. PCT/NL2004/000552		ATTORNEY'S DOCKET NUMBER NY060155-VAN-ES	
20. Other items or information: 10/566878					
The following fees have been submitted				CALCULATIONS PTO USE ONLY	
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... \$300				\$ 300.00	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c))					
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0				\$ 200.00	
All other situations..... \$200					
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b))					
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100				\$ 500.00	
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... \$400					
All other situations..... \$500					
TOTAL OF 21, 22 and 23 =					
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250	\$	
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$ 130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	- 20 =		x \$ 50	\$	
Independent claims	- 3 =		x \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
TOTAL OF ABOVE CALCULATIONS =				\$ 1,130.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
SUBTOTAL =				\$ 1,130.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	
TOTAL NATIONAL FEE =				\$ 1,130.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
TOTAL FEES ENCLOSED =				\$ 1,130.00	
				Amount to be refunded:	\$
				Amount to be charged	\$ 1,130.00

10/566878

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AP2005-01-000000 02 FEB 2006

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 080570 in the amount of \$ 1,130.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 080570. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Customer Number: 00545

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SIGNATURE

Roger Pitt
NAME

46,996
REGISTRATION NUMBER



Kirkpatrick & Lockhart Nicholson Graham LLP

10/566878

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599 Lexington Avenue
New York, NY 10022-6030
212.536.3900
Fax 212.536.3901
www.klmg.com

February 2, 2006

MAIL STOP PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: Andries Johannes Jozef VAN ES; Jan Bastiaan BOUWSTRA; Yuzo TODA
New U.S. Patent Application Filed: Herewith
National Stage of Interntl. App. No. PCT/NL2004/000552 Filed: 4 August 2004
Claiming Priority of European Patent Appln. No. 03077451.7 Filed: 5 August 2003
Attorney Docket: NY060155-VAN-ES
"USE OF RECOMBINANT OR SYNTHETIC GELATIN-LIKE PROTEINS AS STABILISER
IN LYOPHILIZED PHARMACEUTICAL COMPOSITIONS"

SIR:

We enclose herewith:

- [X] Transmittal Letter concerning a filing under 35 U.S.C. 371 w/ Fee Calculation Sheet;
- [X] Duplicate copy of last sheet of Transmittal letter for Fee purposes;
- [X] International Application PCT/NL2004/000552, which includes Specification (16 pp.), Claims (2 pp.), Abstract (1 p.), Sequence Listing (7 pp.);
- [X] Six (6) Sheets of Drawings;
- [X] A Copy of the International Search Report
- [X] Preliminary Amendment; and
- [X] Acknowledgment Postcard.

CORRESPONDENCE ADDRESS INDICATION: Please recognize the following address as the correspondence address: **Customer Number 00545.**

The Commissioner is hereby authorized to charge payment of the fees associated with this communication or credit any overpayment to **Deposit Account No. 080570.**

Applicant hereby petitions under 37 CFR 1.136 or other applicable rule to have the response period extended the number of months necessary to render the attached communication timely if a petition is required.

Respectfully submitted,

By: 

Roger Pitt

Reg. No. 46,996

Tel. No. (212) 536-4867

Express Mail Label:
EV 657136789 US